Food and Drug Administration, HHS

§520.2123b Spectinomycin dihydrochloride pentahydrate soluble powder.

- (a) *Specifications*. The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by growth of *Streptomyces flavopersicus* (var. Abbott) or the same antibiotic substance produced by any other means.
- (b) Sponsor. See No. 061623 in \$510.600(c) of this chapter.
- (c) Special considerations. The quantities of spectinomycin cited in this section refer to the equivalent weight of base activity for the drug.
- (d) Related tolerances. See §556.600 of this chapter.
- (e) Conditions of use. (1) It is administered in the drinking water of growing chickens at 2 grams of spectinomycin per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination It is administered as an aid in the prevention or control of losses due to CRD associated with M. gallisepticum (PPLO). Do not administer to laying chickens. Do not administer within 5 days of slaughter.
- (2) It is administered in the drinking water of floor-raised broiler chickens at 0.5 gram of spectinomycin per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination. It is administered for increased rate of weight gain and improved feed efficiency. Do not administer to laying chickens. Do not administer within 5 days of slaughter.
- (3) It is administered in drinking water of broiler chickens at 1 gram of spectinomycin per gallon of water as the only source of drinking water for the first 3 to 5 days of life as an aid in controlling infectious synovitis due to *Mycoplasma synoviae*. Do not administer to laying chickens. Do not administer within 5 days of slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 56798, Aug. 26, 1980; 66 FR 14073, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003]

§ 520.2123c Spectinomycin dihydrochloride pentahydrate solution.

- (a) *Specifications*. Each milliliter of solution contains 50 milligrams (mg) spectinomycin activity.
- (b) *Sponsors*. See Nos. 000856, 059130, and 061623 in §510.600(c) of this chapter.
- (c) Conditions of use in swine—(1) Amount. Administer 5 mg per pound (lb) of body weight orally twice daily for 3 to 5 days.
- (2) *Indications for use.* For the treatment and control of infectious bacterial enteritis (white scours) associated with *E. coli* in pigs under 4 weeks of age.
- (3) *Limitations*. Do not administer to pigs over 15 lb of body weight or over 4 weeks of age. Do not administer within 21 days of slaughter.

[69 FR 52815, Aug. 30, 2004]

§ 520.2150 Stanozolol oral dosage forms.

§ 520.2150a Stanozolol tablets.

- (a) *Specifications*. Each tablet contains 2 milligrams of stanozolol.
- (b) *Sponsor*. No. 000009 in §510.600(c) of this chapter.
- (c) Conditions of use. (1) Used as an anabolic steroid treatment in dogs and
- (2) Administered orally to cats and small breeds of dogs, ½ to 1 tablet twice daily for several weeks; to large breeds of dogs, 1 to 2 tablets twice daily for several weeks. The tablets may be crushed and administered in feed.
- (3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 46101, Oct. 6, 1975, as amended at 42 FR 36995, July 19, 1977. Redesignated at 50 FR 38114, Sept. 20, 1985, and amended at 55 FR 23076, June 6, 1990]

§ 520.2150b Stanozolol chewable tablets.

- (a) *Specifications*. Each chewable tablet contains 2 milligrams of stanozolol.
- (b) Sponsor. No. 000009 in \$510.600(c) of this chapter.
- (c) *Conditions of use.* (1) Used as an anabolic steroid treatment in dogs.
- (2) Administered orally to small breeds of dogs, ½ to 1 tablet twice daily

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for several weeks; to large breeds of dogs, 1 to 2 tablets twice daily for several weeks.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 38114, Sept. 20, 1985, as amended at 55 FR 23076, June 6, 1990]

§ 520.2158 Streptomycin/dihydrostreptomycin oral dosage forms.

§520.2158a Streptomycin sulfate oral solution.

- (a) *Specifications.* Solution containing 25 percent streptomycin sulfate.
- (b) *Sponsor*. See Nos. 033008 and 055462 in §510.600(c) of this chapter.
- (c) Related tolerances. See §556.610 of this chapter.
- (d) *Conditions of use.* Use in drinking water as follows:
- (1) Calves and swine—(i) Amount. 10 to 15 milligrams per pound (mg/pound) of body weight (1.0 to 1.5 grams per gallon).
- (ii) *Indications for use*. Treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella* spp. susceptible to streptomycin.
- (iii) Limitations. Calves: Do not administer for more than 5 days. Swine: Do not administer for more than 4 days. Prepare fresh solution daily. Calves: Withdraw 2 days before slaughter. As sole source of streptomycin. Warning: Certain strains of bacteria may develop a tolerance for streptomycin. Consult a veterinarian or animal pathologist for diagnosis.
- (2) Chickens—(i) Amount. 10 to 15 mg/pound of body weight (0.6 to 0.9 grams per gallon).
- (ii) *Indications for use.* Treatment of nonspecific infectious enteritis caused by organisms susceptible to streptomycin.
- (iii) *Limitations.* Chickens: Do not administer for more than 5 days. Withdraw 4 days before slaughter. Do not administer to chickens producing eggs for human consumption. Prepare fresh solution daily. As sole source of streptomycin. Warning: Certain strains of bacteria may develop a tolerance for

streptomycin. Consult a veterinarian or animal pathologist for diagnosis.

[57 FR 37327, Aug. 18, 1992, as amended at 58 FR 47211, Sept. 8, 1993; 63 FR 51821, Sept. 29, 1998]

§ 520.2158b Dihydrostreptomycin tablets.

- (a) *Specifications*. Each tablet contains 37.5 milligrams dihydrostreptomycin (as the sulfate) with 375 milligrams chlorhexidine dihydrochloride.
- (b) Sponsor. See No. 000856 in $\S510.600$ (c) of this chapter.
- (c) Related tolerances. See §§ 556.120 and 556.200 of this chapter.
- (d) Conditions of use. Calves—(1) Amount. 150 milligrams of dihydrostreptomycin and 1.5 grams of chlorhexidine dihydrochloride per 100 pounds of body weight per day.
- (2) Indications for use. Treatment of bacterial scours in calves.
- (3) *Limitations.* Administer orally once a day for 5 days; withdraw 3 days before slaughter.

[57 FR 37327, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 520.2158c Dihydrostreptomycin oral suspension.

- (a) *Specifications*. Each milliliter contains 1.25 milligrams dihydrostreptomycin (as the sulfate) with 12.5 milligrams chlorhexidine dihydrochloride.
- (b) *Sponsor.* See No. 000856 in §510.600(c) of this chapter.
- (c) Related tolerances. See $\S 556.120$ and 556.200 of this chapter.
- (d) Conditions of use. Calves—(1) Amount. 150 milligrams of dihydrostreptomycin and 1.5 grams of chlorhexidine dihydrochloride per 100 pounds of body weight per day.
- (2) *Indications for use.* Treatment of bacterial scours in calves.
- (3) *Limitations.* Administer orally once a day for 5 days; withdraw 3 days before slaughter.

[57 FR 37327, Aug. 18, 1992]